UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY PRODUCTS LIABILITY LITIGATION	)	**MDL No. 1:13-md-2419-FDS**
This Document Relates to:	)	**Judge Rya Zobel**
All Cases	)	

AFFIDAVIT OF INGRID S. MARTIN

STATE OF MASSACHUSETTS)
) SS:
COUNTY OF SUFFOLK)

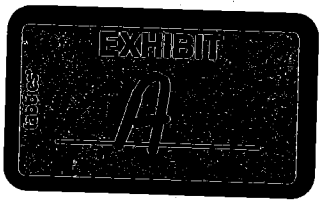
I, INGRID S. MARTIN, do hereby state as follows:

1. I am an attorney in good standing, licensed in the Commonwealth of Massachusetts and practicing at the law firm of Collora LLP ("Collora").

2. Since October 2012, Collora has represented Ameridose in connection with various regulatory matters, including its voluntary recall of products. As part of my work I have spoken to Ameridose personnel and reviewed recall-related paperwork/spreadsheets.

3. On October 31, 2012, Ameridose issued a voluntary recall of all unexpired products remaining in circulation. *See* http://www.fda.gov/Safety/Recalls/ucm326349.htm (Press Release Announcing Recall)

4. On December 17, 2012, the Food and Drug Administration ("FDA") notified Ameridose that its recall was properly deemed a firm initiated recall, and that it had been classified as a "Class II" recall. *See* Ex. B.



5. On June 21, 2013, as the recall was nearing completion, Ameridose sent a letter to the FDA and the Drug Enforcement Administration ("DEA") outlining a process for returning and disposing of the products being held by Ameridose. *See* Ex. C.

6. On July 8, 2013, the DEA's Diversion Program Manager for the New England Field Division informed Ameridose that it approved to the process outlined in the June 21, 2013 letter for disposing of and returning controlled substances. *See* Ex. D.

7. On July 10, 2013, the FDA acknowledged receipt of Ameridose's proposal for returning and disposing of products being held by Ameridose and asked for some additional information regarding the destruction of non-controlled substances. *See* Ex. E.

8. On July 12, 2013 Ameridose notified the FDA that the return of products under the recall had been completed. Ameridose reported that it had achieved a 99% product return rate. *See* Ex. F.

9. On July 16, 2013, the FDA acknowledged receipt of Ameridose's request to terminate the recall and outlined additional information necessary to terminate the recall. *See* Ex. G.

10. On September 30, 2013, Ameridose responded to the FDA's requests for information and provided a plan for how it proposed to dispose of non-controlled products.[1] *See* Ex. H.

11. On October 21, 2013, I spoke by telephone to Susan Liner, the FDA's Recall Coordinator for the New England Region. Ms. Liner informed me that the FDA approved of Ameridose's plan for disposing of its products, subject to the following conditions: (1) the FDA needed an opportunity to verify the inventory before it was destroyed; (2) the FDA wished to be

[1] The letter is dated September 30, 2013, but it was not sent until the following day, October 1, 2013.

given advance notice of where and when products would be destroyed so that the FDA can send staff to observe the destruction. I confirmed this conversation with a follow-up email the same day. *See* Ex. I.

12. To the best of my knowledge and belief there are no further regulatory requirements for Ameridose to complete before notifying FDA of the information in paragraph 10 and then proceeding with the product destruction.

13. To the best of my knowledge and belief the inventory consists of over one half million "units." The material at issue occupies over 3,000 sq. ft. of warehouse space, including over 1,000 square feet of room in the Company's security vaults. This requires the Company to spend time and money assuring its integrity and safety. And approximately half of the recalled products are DEA scheduled drugs, for which there are substantially enhanced security requirements due to the risk of theft.

14. The controlled substances must be stored in vault with limited employee access and monitored by a vault pharmacist, they must be wrapped and labeled to prevent tampering and inventoried weekly for regulatory purposes. The vault is monitored by video camera and motion sensor although these security measures are currently hampered by large number pallets of recalled product of currently stored there.

15. The continued storage of the large volume of recalled products is costly to Ameridose. Those products are now all well beyond their use date of January, 2013, and they have no legal use or market value. The cost of storage includes the cost of a substantial security system which is necessary to ensure that product is not stolen.

16. Since the recall was completed, the DEA has contacted me as counsel for Ameridose and demanded that Ameridose surrender its DEA controlled substance licenses.

17. The DEA also informed counsel for Ameridose that federal regulation requires a DEA controlled substances license for any entity that maintains possession of any controlled substances. In order to effectuate the voluntary surrender of the licenses the DEA has requested that Ameridose dispose of all controlled substances in its possession.

18. To the best of my knowledge and belief, there have been no claims filed against Ameridose relating to the recalled products discussed in this affidavit.

19. To the best of my knowledge and belief, Ameridose is not storing any MPA.

FURTHER AFFIANT SAYETH NAUGHT.

INGRID S. MARTIN

Sworn to before me and subscribed in my presence, this 11th day of April, 2014.

JEAN NOONAN
Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
March 25, 2016

NOTARY PUBLIC
My commission expires: 3/25/16